

# Notice of Allowability

Application No.

10/602,413

Examiner

Eric S. Olson

Applicant(s)

SCHRIER ET AL.

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address--

All claims being allowable, PROSECUTION ON THE MERITS IS (OR REMAINS) CLOSED in this application. If not included herewith (or previously mailed), a Notice of Allowance (PTOL-85) or other appropriate communication will be mailed in due course. **THIS NOTICE OF ALLOWABILITY IS NOT A GRANT OF PATENT RIGHTS.** This application is subject to withdrawal from issue at the initiative of the Office or upon petition by the applicant. See 37 CFR 1.313 and MPEP 1308.

1. ☒ This communication is responsive to Applicant's amendment filed 9/8/2006 and terminal disclaimer filed 9/27/2006.
2. ☒ The allowed claim(s) is/are 2, 3, 58, and 59, now renumbered 1-4.
3. ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
  - a) ☐ All b) ☐ Some\* c) ☐ None of the:
    1. ☐ Certified copies of the priority documents have been received.
    2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
    3. ☐ Copies of the certified copies of the priority documents have been received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

\* Certified copies not received: \_\_\_\_\_.

Applicant has THREE MONTHS FROM THE "MAILING DATE" of this communication to file a reply complying with the requirements noted below. Failure to timely comply will result in ABANDONMENT of this application.

**THIS THREE-MONTH PERIOD IS NOT EXTENDABLE.**

4. ☐ A SUBSTITUTE OATH OR DECLARATION must be submitted. Note the attached EXAMINER'S AMENDMENT or NOTICE OF INFORMAL PATENT APPLICATION (PTO-152) which gives reason(s) why the oath or declaration is deficient.
  5. ☐ CORRECTED DRAWINGS ( as "replacement sheets") must be submitted.
    - (a) ☐ including changes required by the Notice of Draftsperson's Patent Drawing Review ( PTO-948) attached
      - 1) ☐ hereto or 2) ☐ to Paper No./Mail Date \_\_\_\_\_.
    - (b) ☐ including changes required by the attached Examiner's Amendment / Comment or in the Office action of Paper No./Mail Date \_\_\_\_\_.
- Identifying indicia such as the application number (see 37 CFR 1.84(c)) should be written on the drawings in the front (not the back) of each sheet. Replacement sheet(s) should be labeled as such in the header according to 37 CFR 1.121(d).
6. ☐ DEPOSIT OF and/or INFORMATION about the deposit of BIOLOGICAL MATERIAL must be submitted. Note the attached Examiner's comment regarding REQUIREMENT FOR THE DEPOSIT OF BIOLOGICAL MATERIAL.

## Attachment(s)

1. ☐ Notice of References Cited (PTO-892)
2. ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3. ☒ Information Disclosure Statements (PTO/SB/08),  
Paper No./Mail Date ~~20060929~~ June 23, 2003
4. ☐ Examiner's Comment Regarding Requirement for Deposit of Biological Material

5. ☐ Notice of Informal Patent Application
6. ☒ Interview Summary (PTO-413),  
Paper No./Mail Date 20060929.
7. ☒ Examiner's Amendment/Comment
8. ☒ Examiner's Statement of Reasons for Allowance
9. ☐ Other \_\_\_\_\_

SHAOJIA ANNA JIANG, PH.D.  
SUPERVISORY PATENT EXAMINER

**Detailed Action**

This application is a divisional application of 09/952787, filed November 14, 2001, now US patent 6620829, which claims benefit of provisional application 60/241119, filed October 17, 2000. Applicant's amendment, submitted September 8, 2006 is acknowledged wherein claims 1 is amended. Applicant's terminal disclaimer, submitted September 27, 2006, is acknowledged.

Claims 2, 3, 58, and 59 are pending in this application and examined on the merits herein.

The reasons for allowance will be discussed below.

The reasons for allowance and Examiner's amendment are as follows:

### **Examiner's Amendment**

An examiner's amendment to the record appears below. Should the changes and/or additions be unacceptable to applicant, an amendment may be filed as provided by 37 CFR 1.312. To ensure consideration of such an amendment, it MUST be submitted no later than the payment of the issue fee.

The claims are renumbered as follows:

Independent claim 2 is renumbered as claim 1.

Dependant claim 3 is renumbered and amended as follows:

3. 2. The method according to claim ~~2~~ 1, wherein the GABA analog is gabapentin.

Independent claim 58 is renumbered as claim 3.

Dependant claim 59 is renumbered and amended as follows:

59. 4. The method according to claim ~~58~~ 3, wherein the GABA analog is a compound named 3-(1-aminomethylcyclohexylmethyl)-4H-[1,2,4]oxadiazol-5-one hydrochloride.

Additionally, the first paragraph of the specification is amended to read:

"This patent application is a divisional application under 35 U.S.C. § 121 of United States Patent Application No. 09/952,787, filed September 14, 2001, now ~~allowed~~ US patent 6620829, which claims benefit of priority from United States Provisional Patent Application No. 60/241,119, filed October 17, 2000."

***Reasons for Allowance***

Currently, claims 1-4, formerly numbered 2, 3, 58, and 59, are pending in this application.

Claims 1-4, formerly numbered 2, 3, 58, and 59, have been examined on the merits herein.

The claimed method of treating cartilage damage by administering a GABA analog of the defined structure, is not seen to be taught or fairly suggested by the prior art, as discussed below.

Applicant's arguments filed September 9, 2006 with respect to the rejection of claims 58 and 59 under 35 USC 101 double patenting for covering the same scope as claims 4 and 5 of US patent 6620829, of record in the previous office action, have been fully considered and found to be persuasive to remove the rejection as the two sets of claims are not identical in scope. Namely, claims 58 and 59 of the instant application are drawn to a method comprising administering a pharmaceutical composition which claims 4 and 5 of 6620829 are drawn to a method comprising administering a compound. However, claims 4 and 5 of 6620829 anticipate the claimed invention. Thus a non-statutory obviousness-type double patenting rejection of claims 58 and 59 on these grounds is appropriate.

The terminal disclaimer filed on September 27, 2006, disclaiming the terminal portion of any patent granted on this application which would extend beyond the

expiration date of US patent 6620829 has been reviewed and is accepted. The terminal disclaimer has been recorded.

The terminal disclaimer, filed on September 27, 2006 with respect to the potential rejection of claims 58 and 59 under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 4 and 5 of US patent 6620829, has been considered and found to be persuasive. Therefore this rejection is not made.

Reasons for allowance are as follows: The claimed method of treating noninflammatory cartilage damage in a mammal suffering therefrom, consisting essentially of administering to the mammal a therapeutically effective amount of a GABA analog as described in instant claims 2, 3, 58, and 59, now renumbered 1-4, is seen to be novel and non-obvious over the prior art and is directed to subject matter adequately described and enabled by Applicant's specification. For example, written description and enablement are provided by the disclosed experimental results in rat and rabbit models of osteoarthritis disclosed on pp. 207-215. One skilled in the art would be able to practice the claimed invention without performing undue experimentation. Furthermore, it is not known in the art to treat noninflammatory cartilage damage by a method consisting essentially of administering gabapentin or compounds recited in the claims. Although gabapentin is known to possess analgesic properties, and therefore to be useful in providing relief from pain, and although administration of gabapentin could be used to allow certain subjects to undertake a program of well-planned exercise to delay the progression of osteoarthritis, the claimed

invention is drawn specifically to a method in which the administration of the compound is sufficient, by itself, to improve the patient's condition. The substitution, in the amendment submitted September 9, 2006, of the phrase, "consisting essentially of" in place of the phrase "comprising" narrows the scope of the claim to include only methods in which the therapeutic composition is sufficient by itself, in the absence of other factors such as well-planned exercise, to treat cartilage damage in a subject.

Therefore the indicated subject matter is allowable over the prior art. Accordingly, Applicant's amendment submitted September 9, 2006, the terminal disclaimer submitted September 27, 2006, and the accompanying examiner's amendment, are sufficient to remove all rejections made in the prior office action as discussed above and to place the application in condition for allowance.

Any comments considered necessary by Applicant must be submitted no later than the payment of the issue fee and, to avoid processing delays, should preferably accompany the issue fee. Such submissions should be clearly labeled, "Comments on Statement of Reasons for Allowance."

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Eric S. Olson whose telephone number is 571-272-9051. The examiner can normally be reached on Monday-Friday, 8:30-5:00.

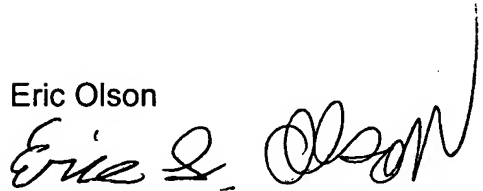
If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Shaojia Anna Jiang can be reached on (571)272-0627. The fax phone

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number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

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9/29/06

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